

- 5     **A package for use in a peritoneal dialysis treatment and a method for manufacturing of such a package**

THE BACKGROUND OF THE INVENTION AND PRIOR ART

10    The present invention relates to a package for use in a peritoneal dialysis treatment and a method for manufacturing of such a package. The invention also relates to a holding member, which is used for organizing a line set in such a package.

15    Such a package, which may be used in a peritoneal dialysis treatment, usually comprises a line set, a drain bag, and a solution bag, which is filled with a dialysis solution. The line set includes one or several tubular line elements and  
20    further elements as one connector connectable to a catheter, which is introduced into the abdomen of the patient by operation, one connector connectable to the drain bag and one connector connectable to the solution bag. The line set also includes flow organizers, such as clamps or at least  
25    one valve, which are used for controlling the flow in the line set. The package usually also comprises a wrapping for encasing the line set and the bags.

Such a package for use in a peritoneal dialysis treatment  
30    must be sterilized. Mostly, steam autoclave sterilization is used for this purpose. The autoclave temperature has to be at least about 120° C during a specified retention time in order to guarantee that all microorganisms are killed. Consequently, the components included in the package have to  
35    be manufactured of materials, which can withstand the autoclave temperature during the retention time. However,

the tubular line elements of the line set and the bags are usually manufactured of PVC. PVC has the property that it withstands the autoclave temperature but becomes relatively soft at this temperature. Therefore, there is a risk that an area of a tubular line element, which is loaded by another line or a component in the package, is deformed during the autoclave sterilization. If an area of a tubular line element of the line set becomes permanently deformed, there is a risk that the flow of the dialysis solution through this line element will be restricted or wholly stopped.

US 6 012 578 shows a package for use in a peritoneal dialysis treatment. The package comprises two bags and a line set. These components are manufactured of polyvinyl chloride (PVC). The bags and the line set are arranged in an overpouch (wrapping). The line set is organized in the package such that several areas of the line elements of the line set are loaded by other parts of the line elements. Consequently, there is a risk that the loaded areas of the line elements are deformed during an autoclave sterilization of the package.

Normally, a patient himself may use such a package for draining fluid from the abdominal cavity and filling fresh dialysis solution to the abdominal cavity. The patient then opens the package and connects the line set, via the connector, to the catheter. The clamps are controlled such that used fluid contained in the abdominal cavity is drained through the line set to the drain bag. Thereafter, the patient adjusts the clamps such that new dialysis solution is supplied from the solution bag to the abdominal cavity via the line set.

#### SUMMARY OF THE INVENTION

The object of the present invention is to provide a package for use in a peritoneal dialysis treatment, which functions

in a reliable manner. A further object is to provide such a package, in which the risk that any part of the tubular line elements in the line set is deformed during an autoclave sterilizing process is substantially eliminated.

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The object is achieved by the package initially defined, which comprises organizing means arranged to organize the line set such that no part of the line set extends across another part of the line set. If a part of the line set  
10 extends across another part of the line set, there is always a risk that an upper part of the line set get in contact with a lower part of the line set and exerts a load thereon with a certain pressure. Since many plastic materials become relatively soft during an autoclave sterilization process,  
15 there is a risk that such a loaded part of the line set is deformed. However, by the organizing of the line set, according to the present invention, this risk may be reduced or even substantially eliminated. Consequently, the risk for a part of the line set being deformed during the autoclave  
20 sterilization is considerably reduced.

According to an embodiment of the invention, the organizing means are arranged to organize the whole line set at substantially the same level. By such an organizing, no part  
25 of the line set extends at a higher level than any other part of the line set. Consequently, no part of the line set could lie on and thus exert a load on another part of the line set. The line set takes up a very small space in a direction perpendicular to said same level. Consequently,  
30 the package may be relatively compact. The organizing means may be arranged to organize the line set such that no part of the tubular line elements is in contact with another part of the tubular line elements. The flexible line elements of a line set are often manufactured in plastic materials,  
35 which become relatively soft during the autoclave sterilization. In such a case, there is a risk for the

contact areas of the line elements to adhere to each other. By the above-mentioned organizing of the line element or elements, this risk is substantially eliminated.

5 According to a further embodiment of the invention, the organizing means are arranged to organize the line set in a spiral-shaped state. In this case, the line set may be wound along a substantially circular path or the like. The end parts of the line set may be arranged radially outside or  
10 radially inside the wound line set. Mostly, the end parts of the line elements are provided with connectors. The space for positioning of the connectors is in these positions relatively large. The risk for a connector to be positioned such that it exerts a load on an adjacent line element is  
15 then negligible.

According to a further embodiment of the invention, at least one tubular line element of the line set is pre-shaped to extend along a desired path. In this way, the flexible line  
20 element automatically attains a desired shape in the package. Preferably, all line elements of the line set may be pre-shaped. Thereby, the whole line set tries to extend along a desired path in which no part of the line set loads on another part of the line set.

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According to a further embodiment of the invention, said organizing means comprises a holding member arranged to hold at least one portion of the first tubular line element in a predetermined position in relation to a portion of the  
30 second tubular line element. By holding the two tubular line elements in a predetermined position in relation to each other, it is possible to organize these two line elements such that no part of the line elements extends across the other line element. The holding member may be arranged to  
35 perform said holding in a detachable manner. Preferably, the holding member holds detachably a portion of all tubular

line elements. The tubular line elements are released from the holding member by the patient when the package is going to be used. The holding member may comprise a first elongated recess, restricted by at least one resilient jaw-shaped member, which is provided with at least one concavity for detachably holding a portion of the tubular line element. The holding member may be applied to the spiral-shaped line set such that portions of the tubular line elements located at different radial distances from the periphery of the spiral-shaped line set will be detachably held in said recess. Advantageously, the holding member is arranged to hold the two portions in a predetermined position in relation to each other, such that the tubular line elements have a substantially parallel extension in the vicinity of the holding member. The risk that said two tubular line elements extend across each other is, at least in the vicinity of the holding member, eliminated.

According to a further embodiment of the invention, the holding member is arranged to hold fixedly a second connector, which is mounted to an end of the second tubular line element. In order to position the holding member in a predetermined position in relation to the line set, it is suitable to connect the holding member to such a component of the line set. The holding member may comprise a hole extending through the holding member. The holding member may be mounted to the second connector by means of said hole, which is arranged to receive the second connector. A suitable adhesive may be applied to the contact surfaces in the hole in order to obtain a fixedly mounting of the holding member to the second connector.

According to another embodiment of the invention, the package comprises a drain bag, wherein the line set is connected to the drain bag. By hygienic reasons, it is suitable that the line set already is connected to the drain

bag in the package. Furthermore, the patient does not need to connect the line set to the drain bag when the package is going to be used. The line set may be connected to the drain bag via a second connector positioned at an outer periphery of the line set. In that position, the risk is minimal that the second connector is placed in a position such it loads on a part of a tubular line element.

According to a preferred embodiment of the invention, the drain bag is foldable to form two folded parts, wherein the line set is applied in the package between the two folded parts of the drain bag. Since the drain bag is empty in the package, it is easy to fold the drain bag. Thereby, the one part of the drain bag may provide a bottom surface, which supports the line set and the other part of the drain bag may provide a surface lying on the top of the line set. The drain bag may be folded at a centerline such that the upper part and the lower part of the drain bag in a folded state have substantially the same size. The weight of the drain bag in an empty state is low. Therefore, the upper part of the drain bag exerts with an insignificant pressure on the line set. The tubular line elements may be manufactured of PVC. PVC is a plastic material having suitable properties for forming the flexible line elements of the line set. Preferably, the drain bag is manufactured of a plastic material, having higher resistance against heat than PVC. Consequently, there is no risk that any part of the drain bag is adhered to the tubular line elements during the autoclave sterilization.

According to another preferred embodiment of the invention, the holding member is arranged to engage detachably one of said folded parts of the drain bag. Thereby, the holding member prevents that an edge area of this part of the drain bag unintentionally is removed from its folded position. The holding member may comprise a second recess restricted by at

least one resilient jaw-shaped member, which is provided with at least one protruding member for engaging detachably said edge area. When the edge area is inserted into the recess, the protruding member grips the edge area and holds it with a resilient force. However, it is relatively easy for a patient to remove the edge area from the recess and release the drain bag from the holding member.

According to a further embodiment of the invention, the package comprises a solution bag, wherein the line set is connected to the solution bag. By hygienic reasons, it is suitable that the line set is connected to the solution bag already in the package. Furthermore, the patient does not need to connect the line set to the solution bag when the package is going to be used. Preferably, the line set is connected to the solution bag via a first connector positioned at an outer periphery of the line set. In this position, there is a minimal risk that the first connector is positioned such that it loads on a part of a tubular line element. Advantageously, the solution bag is filled with a dialysis solution. The drain bag may be applied on top of the solution bag in the package. Thereby, the filled solution bag does not load on the line set, which is enclosed in the folded drain bag.

According to a further embodiment of the invention, the line set comprises at an end a third connector, which is connectable to a coupling member of a patient. Generally, the patient has a catheter introduced into his abdomen by operation. The catheter has an outer flexible tube provided with a connection member at an outer end, which is connectable to the connector of the line set. Preferably, the third connector is positioned at an inner periphery of the line set. The connector is here positioned in a space located in the middle of the wound line set. If this space is sufficiently large for the third connector, there is no

risk that the third connector loads on a part of a tubular line element.

5 According to a further embodiment of the invention, the line set comprises a component in the form of at least one flow organizer, wherein said organizing means is arranged to provide a space sufficient for the flow organizer such that the flow organizer does not load on any part of the tubular line elements. Consequently, the holding member has to  
10 organize the tubular line elements such they are located at a determined distance from each other at least in the vicinity of the flow organizer. Thereby, the flow organizer obtains a space of a sufficient size between adjacent tubular line elements to be positioned into. Preferably, the  
15 package comprises a wrapping for encasing the line set and other included components of the package. In this organized state, the package is exposed to autoclave sterilization.

The object is also achieved by the method initially defined,  
20 which includes the step of organizing the line set such that no part of the line set extends across another part of the line set. Thereby, the line set obtains a shape, which substantially guarantees that no part of the line set loads on another part of the line set and especially not a tubular  
25 line element of the line set. Consequently, the risk that a part of a tubular line element is deformed during the autoclave sterilization is substantially eliminated.

#### BRIEF DESCRIPTION OF THE DRAWINGS

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In the following, preferred embodiments of the invention are described as examples with reference to the attached drawings, in which:



Fig. 1 shows a line set and a drain bag during a first manufacturing step of a the package according to the invention,

Fig. 2 shows a holding member according to the invention,

5 Fig. 3 shows a cross section view of the holding member in a mounted state,

Fig. 4 shows the line set and the drain bag during a second manufacturing step of the package,

Fig. 5 shows the package in an organized state,

10 Fig. 6 shows a second embodiment of a package in an organized state and,

Fig. 7 shows a holding member according to a second embodiment.

15 DETAILED DESCRIPTION OF PREFERRED EMBODIMENTS OF THE INVENTION

Fig. 1 shows a package including a line set 1 for use in a peritoneal dialysis treatment. The line set 1 comprises a  
20 first tubular line element 1a, a second tubular line element 1b and a third tubular line element 1c. The first tubular line element 1a has an extension between a first connector 2, which is connectable to a solution bag 3, and a junction member 4. The second tubular line element 1b has extension  
25 between a second connector 5, which is connectable to a drain bag 6, and the junction member 4. The third tubular line element 1c has an extension between a third connector 7, which is connectable to a patient, and the junction member 4. In order to control the flow in the first tubular  
30 line element 1a, a first clamp member 8a is mounted on a part of the first tubular line element 1a. In order to control the flow in the second tubular line element 1b, a second clamp member 8b is mounted on a part of the second tubular line element 1b. The tubular line elements 1a, b, c  
35 are flexible and they are manufactured of polyvinyl chloride, PVC. Alternatively, the tubular line elements 1a,

b, c will be manufactured of a material comprising polyolefin and thermoplastic elastomer.

PVC is a material having good properties for being used in the flexible line elements 1a, b, c of a line set 1. PVC has the property that it withstands an autoclaving temperature of about 120° C during a required retention time but it becomes relatively soft at this temperature. Therefore, if a part of a tubular line element 1a, b, c is loaded by another tubular line element or component in the package, there is a risk that the loaded part of the line element 1a, b, c will be permanently deformed during the autoclave sterilization. The flow of a fluid through such a deformed part of the tubular line element 1a, b, c risks to be restricted or wholly stopped. Another risk is that a loaded part of a tubular line element 1a, b, c will adhere to the loading line element or the component.

In order to avoid the above-mentioned risks, the line elements 1a, b, c are wound such that the line set 1 obtains a substantially spiral-shaped extension. Furthermore, the whole line set is organized at substantially the same level. In such a wound state, no part of the line set extends across another part of the line set. The first connector 2 to the solution bag 3 and the second connector 5 to the drain bag 5 are positioned at an outer periphery of the wound line set 1. By such an arrangement, the first connector 2 and the second connector 5 are applied in positions in which they do not load on any part of the tubular line elements 1a, b, c. The third connector 7, which is connectable to the patient, is positioned in a space at an inner periphery of the spiral shaped line set 1. In the center of the spiral shaped line set there is a space providing a sufficient size for receiving the third connector 7. In this position, the third connector 7 does not load on any part of the tubular line elements 1a, b, c.

A holding member 9 is used to guarantee the organizing of the line set 1 in the package. The holding member 9 is separately shown in Fig. 2 and in a mounted state in Fig. 3.

5 The holding member 9 has a relatively elongated shape and is provided with a hole 10 at an end portion. The hole 10 extends through the holding member 9. The hole 10 is arranged to receive and hold the second connector 5. The second connector 5 may be fixedly attached in the hole 10 of

10 the holding member by means of an adhesive or the like. When the second connector 5 has been connected to the opening of the drain bag 6, the holding member 9 obtains a desired position in relation to the drain bag 6 in the package.

15 The holding member 9 is provided with a first elongated recess 11 that extends inwardly from an opposite end portion of the holding member 9 in relation to the hole 10. The holding member 9 comprises a lower jaw-shaped portion 11a and an upper jaw-shaped portion 11b. Each of the jaw-shaped

20 portions 11a, b defines a side surface of the elongated recess 11. The lower jaw-shaped portion 11a and the upper jaw-shaped portion 11b comprise three correspondingly shaped concavities 12a, b, c arranged on opposite sides of the recess 11. The innermost concavities 12a of the jaw-shaped

25 portions 11a, b in the recess 11 are arranged to receive a portion of the first tubular line element 1a. The intermediate concavities 12b of the jaw-shaped portions 11a, b are arranged to receive a portion of the second tubular line element 1b. The outermost concavities 12c of the jaw-

30 shaped portions 11a, b are arranged to receive a portion of the third tubular line element 1c. In this case, the concavities 12a, b has a shape in the holding member 9 such that the attached portions of the first tubular line element 1a and the second tubular line element 1b is held in such a

35 way that the line elements 1a, b extend in a parallel direction in the holding member 9. However, the outermost

concavities 12c have a slightly inclined shape in relation to the concavities 12a, b. Therefore, the third line elements 1c obtains a curved extension in the proximity of the outermost concavities 12c. Consequently, the third  
5 connector 7 obtains an angular position in the package such that its front end portion does not load on the adjacent second tubular line element 1b.

The holding member 9 is manufactured of a plastic material  
10 having properties such that the jaw-shaped portions 11a, b obtain a suitable flexibility in a transverse direction in relation to the elongated recess 11. Thereby, it is easy to insert the tubular line elements 1a, b, c into the respective concavities 12a, b, c in the jaw-shaped portions  
15 11a, b. The line elements 1a, b, c are, in an organized state, organized by the holding member 9 such that they are held at a predetermined distance from each other at substantially the same level. Furthermore, the holding member 9 holds the second connector 5 by the hole 10 at  
20 substantially the same level as the tubular line elements 1a, b, c. By the use of a holding member 9 having the above described design, it is possible to organize the whole line set 1 such that no part of the line set 1 extends across another part of the line set 1 in the organized state.  
25 Furthermore, the holding member 9 makes it possible to organize the line set 1 such that no parts of the tubular line elements 1a, b, c are in contact with each other at any place in the package. The holding member 9 guarantees that the tubular line elements 1a, b, c are located at a  
30 predetermined distance from each other. Thereby, a space of a required size is obtained between adjacent tubular line elements 1a, b, c in which the clamps 8a, b will be positioned. Thereby, the clamps 8a, b neither load on any part of the tubular line elements 1a, b, c. In order to  
35 facilitate further the organization of the line set 1, the tubular line elements 1a, b, c are pre-shaped to extend

along a desired path, such as a spiral-like path. Consequently, they automatically try to attain said pre-shaped spiral-like shape, in which no part of the line set 1 loads on another part of the line set 1.

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When the second connector 5 has been connected to the opening in the drain bag 6, the line set 1 is positioned on a first part 6a of drain bag 6, which provides a bottom surface for the line set 1. Thereby it is possible to fold  
10 the drain bag 6 at a centerline 6c, such that a second folded part 6b of the drain bag being positioned above the line set 1, see Fig. 4, and the first folded part 6a in the organized state. The holding member 9 is provided with a second elongated recess 13, which, in a mounted position, is  
15 located above the first recess 11. The holding member 9 comprises an upper jaw-shaped portion 13a and a lower jaw-shaped portion 13b. The lower jaw-shaped portion 13b is identical to the upper jaw-shaped portion 11b of the first recess 11. The upper jaw-shaped portion 13a comprises  
20 protruding members 14a and the lower jaw-shaped portion 13b comprises protruding members 14b. However, the upper protruding members 14a are displaceably arranged in relation to the lower protruding members 14b on the opposite side of the recess 13. The jaw-shaped portions 13a, b has a  
25 flexibility in a transverse direction in relation to the elongated recess 13. Thereby, it is relatively easy to introduce an edge area of the second folded part 6b of the drain bag 6 into recess 13. The jaw-shaped portions 13a, b hold the edge area 6a with a resilient force by means of the  
30 protruding members 14a, b. In a folded, organized state, the first part 6a and the second part 6b of the drain bag 6 are in contact with the line set 1 in the package. Therefore, the drain bag 6 preferably is manufactured of another plastic material than PVC, such as a material comprising  
35 polyolefin and thermoplastic elastomer. The drain bag 6 is manufactured of a plastic material having a higher

resistance against heat than PVC. Thereby, the plastic material of the drain bag 6 does not soften during the autoclaving temperature. Consequently, there is no risk that the tubular line elements 1a, b, c adhere to the drain bag  
5 6. The drain bag 6 may be provided with an embossed pattern.

Fig. 5 shows the package in the organized state to be exposed to autoclave sterilization. The line set 1 and the drain bag 6, which is folded around the line set 1, are in  
10 the package applied on the solution bag 3. The solution bag 3 is filled with a dialysis solution. The first connector 2 is connected to a connection member 15 of the solution bag 3. A number of containers 17 are formed in the solution bag 3. Finally, a wrapping 16 has been wrapped around the  
15 package for completely encasing the line set 1, the bags 3, 6 and the other components of the package.

When the package is to be used for a peritoneal dialysis treatment, the patient initially removes the wrapping 16.  
20 After that the edge portion of the second part 6b is removed from the detachable attachment in the second recess 13 of the holding member 9. The second part 6b of the drain bag is unfolded from its position above the line set 1 such that the line set 1 becomes uncovered. The patient grips the  
25 holding member 9 and separates the line elements 1a, b, c from the detachable attachment in the first recess 11 of the holding member 9. The peritoneal dialysis set is now ready to be used. The connector 7 connects to a catheter of the patient. The patient sets the clamp 8a in a closed position  
30 and the clamp 8b in an open position such that used fluid contained in the abdominal cavity is drained through the third tubular line element 1c and the tubular second line element 1b to the drain bag 6. Thereafter, the patient sets the clamp 8a in an open position and the clamp 8b in a  
35 closed position. Fresh dialysis solution flows now from the solution bag 3, via the first tubular line element 1a and

the third tubular line element 1c, to the abdominal cavity of the patient.

Fig. 6 shows an alternative package in the organized state, which is to be exposed to autoclave sterilization. In this case, the package comprises a flow organizer in the form of a valve 8c for controlling the flow in the first tubular line element 1a and in the second tubular line element 1b. The valve 8c is arranged in a connection between the first tubular line element 1a and the second tubular line element 1b. Consequently, a separate junction member 4 does not need to be used. In the organized package, the valve 8c is positioned at an inner periphery of the spiral-shaped line set 1. Otherwise, the package has a correspondence design as the package shown in Fig. 5.

Fig. 7 shows an alternative embodiment of the holding member 9. It is here visible that the outermost concavity 12c has a slightly inclined shape in relation to the concavities 12a, b. The inclined outermost concavity 12c guarantees that the third line element 1c obtains a curved extension in the proximity of the outermost concavity 12c such that the third connector 7 obtains an angular position in the package. Thereby, the third connector 7 does not load on the adjacent second tubular line element 1b. The upper jaw-shaped portion 13a has here a free end, which is inclined such that the inlet to the second recess 13 obtains a larger size than the remaining part of the second recess 13. Thereby, it is simple to introduce the edge part of the drain bag 6 into the second recess 13.

The present invention is not limited to the embodiments disclosed, but may be varied and modified within the scope of the claims.